

**REMARKS**

Applicants acknowledge receipt of an Office Action dated December 9, 2003. As an initial matter, Applicants note that the PTO appears to have inadvertently indicated that claims 1-42 are pending in the application. Claims 2, 11, 23, 24 and 30-32, however, were cancelled in a supplemental amendment filed on September 12, 2003. In this response, Applicants have cancelled claim 15 without prejudice or disclaimer. Thus, claims 1, 3-10, 12-14, 16-22, 25-29 and 33-42 are currently pending and under consideration.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Rejection Under 35 U.S.C. §103**

On page 2 of the Office Action, the PTO has rejected claims 1-42 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,340,648 or WO 93/04013 in combination with Chistolini *et al.* or Itokazu *et al.* As noted above, claims 2, 11, 23, 24 and 30-32 were previously cancelled without prejudice or disclaimer, and, in this response, Applicants have cancelled claim 15 without prejudice or disclaimer. Accordingly the rejection of these claims under 35 U.S.C. §103(a) is moot. With respect to the remaining claims, Applicants respectfully traverse this rejection for the reasons set forth below.

In contrast to the PTO's suggestion in the Office Action, the refractory article disclosed in W093/04013 is formed from different materials using a different process. This differences in materials and in production process include:

The compositions of the slurry of the present invention and of the invention of W093/04013 are different. Specifically, in W093/04013, the slurry, as disclosed throughout the specification uses a "monomer". In contrast, according to the method of the presently claimed invention, the slurry includes a cross-polymerizable resin "polymer."

With respect to the process of forming the article, the sintering temperature of the present invention and of the invention of W093/04013 are different. Specifically, W093/04013 discloses examples in which a porous article is made at a sintering temperature

of “1300°C or more.” See the Table, on Page 18. If the sintering temperature is “1300°C or more,” “hydroxyapatite” resolves into  $\alpha$ -TCP or calcia. In contrast, according to the presently claimed invention, an “apatite” condition remains unchanged as a result of sintering at a temperature of about 1100°C.

Further, the refractory article of W093/04013 is not intended for the same use as the instantly claimed product. In W093/04013, many materials for the refractory articles are mentioned as follows:

“In the case of a ceramic it may be one or more of alumina, mullite, silicon carbide, . . . hydroxyapatite, . . . Multi-component compositions may be used. Metals or alloys, . . . (page 5, lines 6-1 from below).

Further, many conceivable uses of a porous body are also disclosed as follows:

“. . . catalyst supports, flame supports; gas filters, . . . artificial parts for the body; . . .” (page 10, lines 4-16).

In addition, the specification nowhere refers to artificial bone and only includes the phrase “artificial parts for the human body.” It is not expressly mentioned in detail whether or not the “artificial parts for the human body” is used for internal organs, bones, or other parts. W093/04013 nowhere discloses or suggests that artificial bones for human can be made of hydroxyapatite. Also, there is no suggestion in the description of W093/04013 to introduce cells or the like into the inside of the presently claimed articles.

It should be noted that the invention of W093/04013 is characterized by having a “critical viscosity” as defined in Claims 1 to 5 and 20 to 22.

In an experiment performed by Applicants, a slurry was prepared at Toshiba Ceramics Co., Ltd. as follows:

First, powder of hydroxyapatite 100% with mean particle diameter of about 0.8 $\mu$ m made by Toshiba Ceramics, Co., Ltd., ion exchange water, and polyethylene imine were mixed in the proportion of 9.38:6.67:1 to make a mixture. Next, the mixture was milled by a ball-milling machine for 48 hours to make a slurry.

The slurry was measured by EKO INSTRUMENT CO., LTD. The measured slurry was within the scope of the claims of the present application, but did not have a “critical viscosity,” which is a very important characteristic feature of the invention of W093/04013.

Although, the presently claimed invention and W093/04013 both produce a ceramic porous body by stirring a slurry, the article disclosed in W093/04013 is not formed from the same materials using a similar process and is not intended for the same use as the product of the presently claimed invention. These differences result in fundamental differences in the end product. In addition to the differences based on the different processing temperatures, a porosity of the porous body, a pore diameter, a degree of communication of the pores are different, largely depending on how the slurry is stirred and the degree of gas contained therein. The types of pores are very important features for preferred embodiments of the presently claimed invention.

Examples III and VIII disclosed in W093/04013 show that the porous body made of hydroxyapatite is formed from a slurry. However, Example III does not show a mean pore diameter, although it might be assumed that pore diameters are about 10-16 $\mu$ m or so, because a Buchner funnel having a pore diameter of 10-16 $\mu$ m is used in Example III. In Example VIII, the “product had a mean pore diameter of 24 micrometre.” Both Example III and Example VIII fail to show anything about the state of the pores. Further, there is no explanation as to whether the pore is completely closed opened or opened partially.

According to the presently claimed invention, the mean pore diameter is not less than 100 $\mu$ m and not more than 600 $\mu$ m. This is fundamentally different from of W093/04013.

If the mean pore diameter of WO 093/04013 is about 24 $\mu$ m or so, it is extremely difficult to form not less than four communicating parts (pores) having the size of the mean pore diameter as in the presently claimed invention.

In addition, it is physically impossible to form the communicating pores having the size of not less than 50 $\mu$ m.

For these reasons, Applicants submit that the PTO's reliance on WO 93/04013 is improper. Accordingly, Applicants submit that no combination of WO 93/04013 with any of the other cited references results in the presently claimed invention.

In U.S. Patent 6,340,648, regeneration of bone does not start if the cells do not infiltrate into the pores. It should be noted that, in U.S. Patent 6,340,648, regeneration of bone is not necessarily accelerated only by infiltrating the cells. In this case, sufficient amounts of oxygen or nutrition need to be spread over the cells infiltrated. Otherwise, regeneration does not occur actively. For that purpose, body fluid such as blood must be completely spread in a porous body. In a living body, it is preferable for body fluid to flow in any directions.

According to the presently claimed invention, the large pores having a size larger than the mean pore diameter have a plurality of communicating pores, so that the body fluid can be supplied in any directions. Sufficient nutrition can be also supplied with the cells inside.

U.S. 6,340,648 does not teach or suggest these features of the presently claimed invention.

Itokazu et al. discloses a material in which antibiotic or anticancer drugs are infiltrated in a block of porous hydroxyapatite, which serves as a release material. However, Itokazu et al. fails to resolve the deficiencies of U.S. Patent 6,340,648.

Chistoline et al. does not disclose any porous body having special "pore" characteristics as defined in Claim 1 of the present invention, and, thus, also fails to resolve the deficiencies of U.S. Patent 6,340,648.

In view of the foregoing, Applicants submit that no combination of either WO 093/04013 or U.S. Patent 6,340,648 with either Itozaku et al. or Chistoline et al. teaches or properly suggests the presently claimed invention.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection under 35 U.S.C. §103.

### CONCLUSION

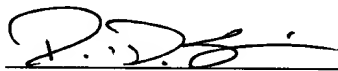
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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